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Ethics Committees

BIOETHICS COMMITTEES AND EXAMINING CONSENT WITHIN THE PATIENT-PHYSICIAN RELATIONSHIP IN TURKEY

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Abstract: Clinical exercises include questions about a physician's behaviour, decision making process, values, rights and responsibilities, as much as the scientific-technical questions concerning the disease. Some of these questions may be easily answered, for there are well-constructed activity options that have found widespread acceptance regarding what has to be done. However, it is quite difficult to answer the questions with problematic options, or the ones on which a compromised attitude is not present.

Patient participation in treatment-related decision-making has been promoted as being ethically and clinically desirable in Western countries. Several studies have indicated that patient participation in decision-making has a positive influence on their health outcomes, thereby increasing patient satisfaction regarding medical care and promoting patient autonomy. Over the last decade, patient involvement in treatment-related decision-making has been widely advocated in Turkey, where patient-physician encounters are still under the influence of the long-standing tradition of paternalism. Despite this profound change in clinical practice, studies investigating the actual preferences of Turkish people regarding involvement in treatment-related decision-making are limited.

In Turkey, to protect the rights of patients, current Govermental requirements mandate that all human biomedical research and medical intervention be accompanied by a consent form that contains the information necessary for an informed decision. In addition, they require

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that the information provided to the subject or the representative shall be explained in appropriate language. Especially after the new regulations in the Turkish Penal Code, physicians and nurses have started to be more sensitive towards informed consent and have become more conscious about their responsibilities. It has started to be questioned more, and as a result, the problems experienced about patient consent in medical applications created new ethical dilemmas.

Informed consent is acknowledged to be the most essential constituent of patient rights today. In this paper, after introducing a general overview of the significance and requirements of informed consent, we will consecutively discuss the decision making and informed consent process, legal arrangements concerning this issue in Turkey, the approaches of physicians and patients towards the topic, and regarding informed consent, we will discuss the responsibilities of hospital ethics committees.

Keywords: Physician-Patient Relations; Patient Rights; Informed Consent; Hospital Ethics Committees; Intercultural Biomedical Ethics.

INTRODUCTION

Despite the fact that patient involvement in treatment-related decision-making has been widely advocated and promoted in both clinical and policy-making settings in many developed countries, research conducted in the US, Canada, and the UK revealed that people's preferences regarding their role in the decision-making process vary substantially. Some research further indicated that the preference for handing over the control to the physician is significantly greater when the situation involves potential mortality or when the respondents' health status is deteriorating[1, 2, 3]. Moreover, other studies have revealed that the relationship between patient preferences regarding their involvement in the

1. Degner LF, Sloan JA: Decision-making during serious illness: what role do patients really want to play? *J Clin Epidemiol* 1992, 45(9):941-950.

2. Arora NK, McHorney CA: Patient preferences for medical decision making: who really wants to participate? *Med Care* 2000, 38(3):335-341.

3. Levinson W, Kao A, Kuby A, Thisted RA: Not all patients want to participate in decision making: a national study of public preferences. *J Gen Intern Med* 2005, 20(6):531-535.

decision-making process and their actual level of involvement is a strong indicator of patient satisfaction[4, 5, 6]. Thus, it has been increasingly emphasised that healthcare professionals need to assess individual patient preferences in order to provide tailor-made care accordingly and merely pressurising patients to decide on a treatment option could have negative psychosocial consequences, if the patient does not wish to be the final decision maker.

If we start with a question: Is there a preferred communication model with reference to the physician – patient relationship? It is obvious that this question could not be answered easily, because it is supposed that, for different clinical conditions and different societies, different models should be applied. Indeed, in different times, different communication models could serve the physician or the patient. If we were to raise several other questions, then these could be the following: Are the priorities and evaluation of ethical principles regarding clinical ethics in Turkey, different from the Western applications? Should the activities that have been developed in the Western World, like informed participation and respect for individual authority, be understood as universal values in terms of intercultural biomedical ethics? Or, should they be left to cultural interpretation and application?

The term "patient rights" in the field of clinical medical ethics is the product of this specific relationship, which has been reshaped on the grounds of "mutual participation." Educational, cultural and economical levels of the patient have an impact on their attitude about taking over the responsibility for their own health care. Therefore, the patient/patient's relatives should be instructed in a manner to improve the level of responsibility over their problems, and to improve their behavior, to help the patient perceive the concept of autonomy clearly.

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4. Keating NL, Guadagnoli E, Landrum MB, Borbas C, Weeks JC: Treatment decision making in early-stage breast cancer: should surgeons match patients' desired level of involvement? *J Clin Oncol* 2002, 20(6):1473-1479.

5. Lantz PM, Janz NK, Fagerlin A, Schwartz K, Liu LH, Lakhani I, Salem B, Katz SJ: Satisfaction with surgery outcomes and the decision process in a population-based sample of women with breast cancer. *Health Serv Res* 2005, 40(3):745-767.

6. Yoshiko Watanabe, Miyako Takahashi† and Ichiro Kai, Japanese cancer patient participation in and satisfaction with treatment-related decision-making: A qualitative study. *BMC Public Health* 2008, 8:77.

In fact, the definitions and concepts related to bioethics and medical ethics come from Western literature, no matter how much it is emphasized that ethics and ethical values are universal, the differences between societies are unavoidable.

"COLLECTIVE AUTONOMY"

We know most Western countries have moved towards a "patient autonomy model" in which full disclosure and respect for the patient's wishes and decisions is paramount.

Many quantitative and qualitative studies conducted in Asian countries have put forward that, particularly in some clinical situations, instead of using a "patient autonomy model" and/or the continuation of medical paternalism in physician-patient communication, using a "family oriented model" is more effective. In Turkey, as in most developing countries, Ethics committees were initiated with pressures from the Western scientific community. Since their formation, ECs have faced many problems because of an underdeveloped scientific culture and the absence of established ethical standards. On one hand, the standards of the ECs in the developed world seemed too hard to achieve; on the other, some of the international regulatory rules, such as respect for autonomy, are not culturally sensitive. Respect for autonomy is a good example to examine in the Turkish context. The social construct of Turkish society is not based on the Western concept of autonomy; it is commonly based on "collective autonomy," which is completely different from its Western meaning. The cultural interpretation of any concept is the perception of the concept as referred to in its cultural connections with other concepts.

THE DECISION MAKING AND INFORMED CONSENT PROCESS

The notion of **consent** in biomedical ethics usually means a voluntary, uncoerced decision, made by a competent autonomous person, on the basis that the consequences told should be accepted rather than rejected. In a way it is a proposed course of action. The basic requirements of an informed consent are that, patients should understand the information, they must be competent to make a decision, and they must arrive at their decision without being coerced or manipulated by the medical staff or others[7]. A truly informed consent requires

7. Faden RR, Beauchamp TL. A history and theory of informed consent. Oxford: Oxford University Press, 1986.

full disclosure of all relevant information by the physician, a competence of the patient to appreciate what the information signifies, understanding the facts and issues by the patient and a voluntary non-coerced choice made by the patient leading to an autonomous authorisation for treatment are crucial; but however, each of these conditions is always hard to fulfil, making a fully informed consent is seldom realised or, if ever, possible.

Faden and Beauchamp - whose influential analysis of informed consent forms the basis of much of this essay – identify two distinct meanings of the term. The first nuance -which we call the moral sense of the term - defines informed consent as an "autonomous authorization", meaning one's participation in research. A second nuance -which we refer to as the socio-legal sense of the term- defines informed consent as a "legally or institutionally effective (sometimes misleadingly called valid) authorization"[7].

Informed consent empowers patients and allows them to take part in critical decision making, as long as they agree to play an active part and have the capacity to do so[8].

In the Pakistani context, a country that embodies cultural characteristics similar to Turkey, there are several other factors to consider in crucial decision making situations. In some cases, the patient opts to exclude himself/herself (themselves) from receiving information and participating in discussions regarding his/her management, delegating family members to make the decisions. Alternatively s/he may invite his/her physician to use his/her best judgment and choose the best option for him/her. In other situations, the family members may insist on excluding the patient from the decision making loop. A tradition of living in extended families, often with shared incomes, strengthens the role of the family in major decision making situations like selection of marriage partners, financial transactions, and in making decisions about medical treatment[9].

Informed consent, as a procedure, is one of the most concrete appearances of the respect for autonomy in the practice of medicine. When this procedure was introduced in Turkey, many additional problems arose. One of the most difficult problems was the unwillingness of individuals to participate in the process

8. Worthington R. Clinical issues on consent: some philosophical concerns. *J Med Ethics* 2002; 28: 377–380.

9. Jafarey AM, Farooqui A. Informed consent in the Pakistani milieu: the physician's perspective. *J Med Ethics* 2005; 31: 93–96.

as autonomous agents. In Turkish society, the smallest unit that can function as an autonomous entity is the family. Moreover, it is necessary to understand family as a larger unit than is usually conceptualized in Western societies. The nuclear family is a phenomenon that is limited to a few large cities in Turkey. A Turkish family generally consists of grandparents and other blood relatives. Even very close friends who are not bound to the family with blood relations can be assumed as family members. The family does not act alone in the decision-making process. Whatever the dimensions of the decision-making unit, the most interesting feature of the social construct of Turkish society is the undetermined nature of individual boundaries and the complexity of interpersonal relationships. The crucial point for health professionals is that the individual expects the entire culturally structured decision-making unit to be involved in the decision-making process.

Not only are the health professionals inexperienced in dealing with the concept of autonomy and its applications, but they are unfamiliar with the concept as well. Additionally, the Western definition of autonomy does not provide a solution for handling the expanded decision-making unit. In fact, nothing in the definition recognizes the situation. The problem of implementing informed consent makes it apparent that there is no tradition of respect for autonomy in the daily practice of medicine and biomedical research in Turkey.

In the Turkish context, there are several factors to be considered in crucial decision making situations;

1. In some cases, the patient opts to exclude himself/herself from receiving information and participating in discussions regarding his/her management, and instead delegates the decision to family members.
2. Alternatively s/he may invite his/her physician to use his/her best judgment and choose the best option for him/her.
3. In other situations, the family members may insist on excluding the patient from the decision making loop. A tradition of living in extended families, often with shared incomes, strengthens the role of the family in major decision making situations like selection of marriage partners, financial transactions, and in making decisions about medical treatment.

In the physician-patient relationships in our country, the one who is primarily responsible for making decisions about the patient's treatment is not the patient but the patient's next of kin. In particular when the diagnosis is cancer this

situation is very clear. The family members, who find the liberty to make decisions in the name of the patient, argue that if the patient were told their prognosis, it will be detrimental for their morale and their psychology will be negatively affected and even their condition would worsen. On the other hand the physician's negative attitudes also play a role in this process. Sometimes the diagnosis is known by everyone except the patient but the patient is not able to receive this information without requesting it.

Physician's attitudes toward patients with cancer have changed rapidly in recent years. As a result of this change, there has also been a shift in physician-patient communication models and it has brought an important patient-centered look to the field of medical ethics and to clinical medicine. Two separate negative attitudes have been observed from physicians who take care of cancer patients. The first is the excessive guardian, protector, paternalistic attitude, that the physician actually tries to prevent death, and where there is a denial of death. The denial of death is also observed in another attitude in that the physician escapes from and distances himself/herself from the patient[10].

In oncologic illnesses telling the patient the truth is a process that requires much more effort and it is more complex than just giving simple information. In cases of cancer, illnesses in the terminal phase, some neurologic diseases, and in AIDS, physicians and other health care workers experience some dilemmas, arguments and problems, on the subjects of, whether to tell or not to tell the truth, or how to tell it, and who should do this. As there are some physicians who defend that the patient should be told the truth no matter what the situation is, there are also others who defend that the truth should be withheld to not cause distress to the patient. The thought that underlies not telling the diagnosis to the cancer patient is exempt from the belief that the cancer patient will not be able to endure this information, and they will experience some additional emotional problems, and that it will negatively affect the prognosis of the illness. However, from another point, informing the patient at every phase of the illness is important for patient's adaptation to the process to come. On the basis of this a participative communication that includes active listening to the patient and feeling empathy is found. The problem of telling the patient the medical truth is affected by country's' sociocultural and economic structures, and by medical practice and the form of health structures.

10. Buken NO. "Truth-telling information and communication with cancer patients in Turkey". *Journal of International Society for the History of Islamic Medicine (JISHIM)*, October 2003, Vol. 2, No:4, pg: 31–37.

SOME INFERENCES ABOUT INFORMED CONSENT IN TURKEY

Together with the characteristics of the physician-patient relationship and the expectations of the physician and patient; the physician's duties and responsibilities, the process of informed consent and ethical medical practice, and if it is consistent with legal standards or not are also important. In this relationship, the goals of the physician-patient interaction, the physician's requirements, the role of the patient's values and the concept of patient autonomy are other extremely important topics to be held.

In the course of solving clinical ethical problems in our country, some questions can be asked, (repeated) such as: If the guiding ethical principles' priority and evaluation is different from those of the West? Can the practice in the West that gives priority to the developed well-informed participation and as a part of that the principle of respect for a person's autonomy be left to the interpretation of one's culture and practices? When we look at those questions from the aspect of basic ethical principles, we can say that it is necessary to agree on the concepts of universal values such as respect for an individual's autonomy that has developed in the West. We cannot leave to the culture's own interpretation and practices the need to examine basic ethical principles; that is, the evaluation and structure of ethical principles in our country related to our subject will not be any different than that in the US, Canada and Western European countries. However there can be a difference in the prioritizing and weighting of the principles. For example, because of the structure of society, our customs and traditions and our sociocultural structure, the principles of "do no harm" and "beneficence" take priority for us over the principles of "respect for autonomy and justice". In the Turkish culture, for example, these principles are not at odds with those of the West. We believe that the difference lies in the priority and weight given to each of those principles; such as patient rights, wishes of the family, and interests of the society as a whole. Even within the same culture, one rigid model may not suit all patients and relatives, and a great degree of flexibility and skill needs to be exercised by the practicing physician. As referred to before, effective physician-patient communication is far more complex than by just giving simple information. Many authors in the field of medical ethics have formulated new concepts when it comes to deal with those principles.

This situation also creates the substructure for hiding the diagnosis of cancer from patients. In that manner, in oncology clinics, as it is often witnessed, everyone knows the patient's diagnosis and the treatment that will be given,

except the patient. Not even one patient (even if they request) will be told the truth and is left to its natural process. The majority of the patient's next of kin take an active role in the process of hiding this truth. As in other countries that have a clear paternalistic societal structure, also seen in our country, the physician generally plays an authoritative role figure in the physician-patient relationship. In this way whether it is natural or not, the relationship between physician and patient, rather than being collaborative, always one is directing the other. As there are other examples of this type that is often found in the society and in the every area of life, it is something that has been based on that and this type of physician-patient relationship is not regarded as strange and the majority of the population does not see any need to change the existing system. The majority of the patients in our country during medical treatment are not in the position to be "knowledgeable and effective participants in the treatment." Conditions like cancer which require a continuous collaborative relationship between the physician and patient do not change this fact. Patients try to get information about the clinical diagnosis and treatment process from their nurses or interns. However, particularly in chronic illnesses, it is a foremost condition for a "collaborative" type of relationship where the treatment method is chosen according to the patient's values and to make sure that the patient is informed about possible risks, and when the patient requests this information, that they could make the most appropriate choice based on their own values, knowing their own rights in this process. In our country the patient accepts that the physician is the "authority" with information, experience and expertise. The patients do not think they have the right to ask questions, but that they have to answer every kind of question that is asked and that they are forced to accept every kind of treatment the physician recommends.

Requests for information and desire for active participation in their treatment is minimal. Physicians also consider that patients generally have a lower sociocultural and intellectual level and for this reason there is no place for this time-consuming practice of informed consent, and continue the belief that they will always make the right decision for the patient and also the social security system to which the patient is bound, does not offer many choices for treatment. For this reason we could assume that most physicians are not skilled at cooperating with their patients, in establishing or maintaining a collaborative relationship with them and also the patients do not have any expectations about the process. When a request for a relationship like this does not come from the patient, it is important that the physician should initiate it. However before everything, the physician must believe that this kind of relationship is beneficial

and that there is a value involved in helping the patients to be effective participants[11, 12].

THE PROBLEM OF RESPECT FOR AUTONOMY AND INFORMED CONSENT

A brief review of the nature of Turkish society will give an adequate account of the situation that is very similar in many developing countries. Turkey is a developing country, and its social structure resembles that of Eastern cultures. With regard to our subject matter, it means that autonomy is not a characteristic of individuals in those societies, at least not in a way that it is defined and understood in the Western world. To a certain extent, the problems of implanting autonomy in everyday practice of medicine and research on human subjects in Turkey are applicable to other Eastern cultures and to developing countries alike. For Turkey, autonomy is one of the most interesting concepts to come out of the imported package of biomedical values from the Western world, and it is the most frequently addressed concept in the study of biomedical ethics in Turkey. Initially, academicians had difficulty in fully understanding the concept of autonomy, foreseeing its applications in practice, and appreciating the overall consequences for medicine and research.

Although these difficulties still exist, it is generally accepted that autonomy, as a concept, is a basic element of Western biomedical ethics and that most of the procedures of the developed world originate from this concept. Without autonomy, it would not be possible to decode Western bioethical discourse. Naturally, the next step for developing countries is to introduce this concept to health professionals, adopt the procedures stemming from it, and move a step closer to the ethical practices of modern medicine.

With an insight into the social state since the founding of the Republic, the understanding that accepts the government's constitutional responsibility for health, has changed with the reflections of globalization and has been reshaped by the government's binding responsibility for health care service; being evenhanded to all citizens, accessible to all, high-quality, free of charge. The

11. Büken NÖ. "Turkey's Position Regarding Clinical Drug Trials". *Clinical Research and Regulatory Affairs*, 2003, Volume 20, Issue 3, pages: 349–355.

12. Buken NO. Buken E. The Legal and Ethical Aspects of Medical Malpractice in Turkey. Selected Legislation and Jurisprudence. *The European Journal of Health Law*, 2003; 10 (2): 199–214.

result of the government cutting resources that were set aside for public health services is that public health services have come to an agonizing point. There is now an understanding by patients and their next of kin -reinforced by the media and, for many reasons, the news brings to the forefront- that the only responsible party for the problems arising, and experienced by the health care system are a result of the physicians and health care personnel. The relationship between health professionals and those seeking health care has completely changed, it has become dominated by relationships between the "physician/ businessman/ assistant" who gives service to a customer and the "customer" who is trying to get the service.[12, 13].

The 17th Article of Turkish Constitution states that "Except for situations of medical necessity and other conditions written in the law, the entirety of a person's body cannot be touched and they cannot be forced to be a medical subject without their permission." The patient is considered to have given their permission with a signature during admission in our country but separate consent is not obtained for medical procedures. According to the related article in the Patients' Bill of Rights, "The patient's consent is necessary for medical procedures. If the patient is a child or not legally responsible, the permission is obtained from their parent or guardian. In situations when the patient's parent or guardian is not available or the patient does not have the ability to make a statement this condition is not demanded. Other than in life threatening situations, it is possible to withdraw permission. Patients have the right to refuse treatment except in situations of legal requirement. In addition in the Patients' Bill of Rights there are subcategories for consent such as consent when implementing treatment methods that are not accepted in practice, consent for the removal of organ and tissue, consent in family planning services, consent in clinical drug trials, consent for children and those without representation[12, 14].

A frequent source of problems experienced between patients and physicians in our country is the failure to inform the patient. According to the related article in the Patients' Bill of Rights the patient has the right to be informed about medical procedures, probable contraindications, course of the disease,

13. Buken N.O. Physician Errors Tied to Patient's Rights, 3rd Medical Ethics Symposium Proceedings Book. Sahinoglu S. *et al.* (Eds). *Bioethics Society Publication*, No:3, Ankara, Turkey, 1998: 47–51.

14. Saglik Bakanligi Hasta Haklari Yönetmeligi (in Turkish) (Turkish Patients' Bill of Rights, MoH), 1998.

alternative treatments and the probable result of refusing treatment, and the result of the disease. A legal representative has this right for patients who are children or do not have legal capacity. In addition, patients can request that the information about themselves should not be given to their family or next of kin. When it is necessary to inform, a translator can be used in a language that the patient will understand. Patients or their legal representative can examine their file and records and can make a copy. They can request a correction of and an explanation of medical and personal information. These records can only be seen by the patient and people directly providing care to the patient[12, 14].

In addition, the traditional feelings of respect and gratitude to the physician and health care institution affect patients' behavior. In fact it is an illusion for many patients to evaluate the quality of the health care that they were able to reach with countless difficulties. This situation creates an obstacle to a societal consciousness on the subject both of patient rights and of precautions that can be taken in the face of medical malpractice. However health care services are no longer provided by some foundations and institutions with charitable intentions as in Ottoman times. Health care services are a large sector globally and nationally. The recipients of health care pay for the services indirectly or directly. There is another saying that the patient who receives health care pays the bill for the health care service (physician, nurse, hospital, health clinic, *etc.*) either directly or with medical insurance premiums or with taxes. Citizens need to have the understanding that "I am paying for your bill" or "I am paying taxes, medical insurance premiums, for this reason I have a right to receive good and quality health care[15]."

During the process of benefitting from the health care system, for patients to be able to receive care from health care institutions they must follow a very confusing path. In particular if their problem is not resolved in a primary care institution they must be transferred by that institution to a secondary care institution. This is called the transfer system. However this transfer system is not functioning in our country. Patients with problems that could be solved in health clinics are being transferred to a hospital, even to a teaching and research hospital. This situation is a reason for the increase in patient intensity in these receiving hospitals. Patient intensity makes it difficult to give care in the manner clarified in the Patients' Bill of Rights. It opens the door to abuse.

15. Saglik Bakanligi Tibbi Deontoloji Tuzugu (in Turkish) (Turkish Medical Deontology Regulation, MoH), 1960.

CONCLUSIONS

Bioethics, as a social movement, had its inception in industrialized countries during the mid-twentieth century and supplemented the professional ethics of physicians and nurses with clinical or applied ethics by addressing practical issues[16, 17].

At this practical level, it was obvious that given the advances made by life and the health sciences, as well as by innovative biotechnologies, there would be a growing need to make difficult moral choices. Health care institutions (mostly at the local level), as well as government and policy agencies (at the national level), soon recognized the importance of developing more formal mechanisms to address and work to resolve ethically charged or value-laden problems in the rapidly shifting dynamics of everyday health care and health policy. At the very least, many leaders of the scientific community thought that the establishment of various forms of bioethics committees would be a significant first step toward initiating discussions and debates on a plethora of contemporary bioethical issues[16].

A bioethics committee is a committee that systematically and continually addresses the ethical dimensions of (a) the health sciences, (b) the life sciences and (c) innovative health policies. A bioethics committee is typically composed of a range of experts, is usually multidisciplinary and its members employ a variety of approaches to work toward the resolution of bioethical issues and problems, especially moral or bioethical dilemmas. Moreover, the members of these committees not only become more sensitive to ethical dilemmas but also, in time, develop the knowledge and skills required to deal more effectively with them, frequently finding ways to resolve what may at first appear to be intractable dilemmas[16, 17].

The need to reflect on the moral dimension of advances in science and technology, as well as the desire to enhance the public's health has, in many areas of the world, led to the establishment of various forms of Bioethics Committees.

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16. Establishing Bioethics Committees, Guide No: I, *UNESCO*, Published in 2005, France, pg: 12- 15.

17. Buken NO. Buken E. International Researches, Fundamental Dilemmas in Research Ethics and Ethics Committees, *Syndrom Journal*, 20(7–8): 37- 47, 2008.

There was no Ethics Committee in Turkey until the 1980s. In those years the scientific journals asked for an Ethics Committee approval from the researchers, which have played a fundamental role in setting up these Committees in Turkey. The requirement for local ethics committee approval in multi centre researches was also a pushing factor for it. The first research ethics committees were set up at Hacettepe University Medical Faculty 1986. These were only ad hoc committees dealing with ethical issues in biomedical research. In Turkey, there was no legal regulation of research on human beings until 1993. In that year, "The Regulation Relating to Drug Research" was issued. The main objectives of the regulation were to establish a central ethics committee and local ethics committees, and to provide an administrative control. According to this regulation, there are two types of ethics committees, the (central) ethics committee and the local ethics committees. These two types of committees are different from each other. Local ethics committees are established at medical institutions where clinical studies are conducted, and generally in universities.

The ethics committee is constituted within the Ministry of Health and its members are appointed by the Ministry. A two-step control system is in use for research on human beings in Turkey. Those willing to conduct medical research on human beings have to receive approval first from the local ethics committee, and then from the central ethics committee. Regulation Regarding Clinical Trials (No: 27089) came into force in December, 2008 and governs clinical trials. The objective of this Regulation is to set forth the procedures and principles regarding the achievement of scientific and ethical standards pertaining to topics such as the design, conduct, record keeping, reporting, validity and other aspects of clinical trials to be conducted on volunteer humans within the framework of European Union standards and Good Clinical Practice and to the protection of these volunteers within the scope of the said Regulation. Article 90 of the *New Turkish Penal Code (*No. 5237), which came into force on April 2005, governs research on human beings. The Article stipulates the conduct of research on conditions such as not violating human well-being and dignity. Now, there are 87 REC's in Turkey ; 47 of them were established in University Hospitals and 40 of them were established in Ministery of Health Hospitals[17,18,19].

'Health care/hospital ethics committees' have been established in many countries around the word. The main goal of these committees is to provide ethics

18. A New Turkish Penal Code (TPC), No. 5237, 2005.

19. Buken NO. Clinical Research Ethics Committees, *Syndrom Journal,* 20(3–4): 61–70, 2008.

consultation services to clinical professionals who are working in hospitals. The development process of these committees differs from country to country and from one hospital to another. During the years the establishment and implementation of ethics committees in the area of hospitals enact many changes[17].

In Turkey, the idea of establishing ethics committees in hospitals is even newer. For ethical decision making and to give ethical consultation, it is necessary for more HEC's to be established in Turkey.

This increase in the tendency towards the issue of informed consent in Turkey brings along the necessity to determine the place of the standardization of the informed consent process more clearly in the country's current health system and to establish the standard applications more effectively on an institutional basis. Furthermore, it should be emphasized more that since its publication by the Ministry of Health, Patient Rights Regulation has put an end to the traditional approach to patients in medical applications and brought equal responsibilities. In this process that started in 1998, an intensive effort has been put both in-medical education and in-service training for the adoption of informed consent. Especially in university hospitals, useful guiding suggestions were given by medical ethics departments, medicine research local ethics committees and several hospital ethics committees are in the process of handling the issue. In order to increase the sensitivity and consciousness of health care providers towards informed consent, many education activities were organized by the Turkish Medical Association and local chambers of medical doctors.

The Ministry of Health's study initiated in 2007 to renew the informed consent forms used in the hospitals in Turkey is still in progress. Alongside these attempts, many associations of clinical speciality are trying to provide support to their members by forming committees for the standardization of informed consent forms and publishing the standard information brochures they have prepared and the informed consent forms on their websites.

In Turkey, there are continuing efforts for the enactment of new legislative provisions concerning research and biomedical ethics, within the framework of progress towards integration with the European Union.

Consequently, as a result of all these education studies and activities carried out to increase the consciousness, sensitivity and information of health care providers in our country about informed consent, it will be possible to enable the integration of our health system into the developed medical technologies

derived especially from the West and also protect the patients' rights and patients' autonomy.